

PSJ17 Exh 121



Document Number: SOP-8279

Document Title: SUSPICIOUS ORDER MONITORING - CUSTOMER DUE DILIGENCE



Revision Number: 01

Vault: PA SOPS

Effective Date: 18 Jun 2018

Signature Manifest**Document Number:** SOP-8279**Revision:** 01**Title:** SUSPICIOUS ORDER MONITORING - CUSTOMER DUE DILIGENCE**SOPDEAMULTI1-FEB2018-JR-0****DC Preview**

Name/Signature	Title	Date	Meaning/Reason
JAMIE L. RAMOS (JLRAMOS)		12 Feb 2018, 10:24:15 AM	Approved

Requestor/Author

Name/Signature	Title	Date	Meaning/Reason
KELLEY SHAW (KSHAW02)		15 Feb 2018, 10:44:22 AM	Approved

Cumulative Mgmt

Name/Signature	Title	Date	Meaning/Reason
COLLEEN MCGINN (CMCGINN)		19 Feb 2018, 03:06:22 PM	Approved
VALERIE HAMNING (VHAMNING)		22 Feb 2018, 09:36:40 AM	Approved

DC Release

Name/Signature	Title	Date	Meaning/Reason
JAMIE L. RAMOS (JLRAMOS)		07 Jun 2018, 02:15:38 PM	Approved

SOP #:	SOP- 8279
TITLE:	Suspicious Order Monitoring – Customer Due Diligence

1. PURPOSE

To establish a procedure to obtain information about new and existing customers who order controlled substances to determine their level of compliance with DEA regulations, specifically information regarding Suspicious Order Monitoring.

2. SCOPE

These procedures apply to the following TEVA Pharmaceuticals personnel:

	North Wales, PA	New Britain, PA
DEA Compliance & Diversion Operations	X	X
Customer Service	X	

DEA Compliance personnel will be responsible for conducting all due diligence investigations on new and existing accounts which includes questionnaires, site visits, risk analysis and maintenance on customer compliance files.

DEA Compliance refers to the Department for overseeing controlled substance activities in the U.S. All DEA-compliance employees at other locations are considered in scope.

As part of this effort, all TEVA associates are expected to report any suspect activity related to new and existing customer accounts to the DEA Compliance Department in a timely manner.

3. SUMMARY OF REVISIONS

1. Reference to "SORDS" changed to "DefOPS"
2. "Pended Orders" definition expanded to clarify that only DEA Compliance personnel determines whether an order is of unusual size, pattern or frequency.

4. REFERENCES

"Know Your Customer Policy"

"It is fundamental for sound operations that handlers take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently, identify those transactions conducted by their customers that are suspicious in nature."

http://www.deadiversion.usdoj.gov/chem_prog/susp.htm#ela

SOP #:	SOP- 8279
TITLE:	Suspicious Order Monitoring – Customer Due Diligence

5. DEFINITIONS

DEA: Abbreviation for the Drug Enforcement Administration

SOM: Abbreviation for Suspicious Order Monitoring

DefOPS: The Acronym for TEVA's SOM Electronic Monitor System

SUSPICIOUS ORDERS: Includes but not limited to orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

DBA: Abbreviation for Doing Business As

PENDED ORDERS: Orders that have been stopped in real time because they breached Teva's SOM algorithm. "Pended" orders are deemed "on hold" until they are investigated. DEA Compliance personnel are the only employees that can review pended orders to determine whether they are of unusual size, pattern and/or frequency, and approve, or report as suspicious, pended orders for DEA Holds.

SUSPICIOUS ORDER OVERSIGHT TEAM: A predetermined team comprised of a representative from DEA Compliance, Customer Service, Legal and Customer Account Management. Certain situations may warrant the addition of other business units at the request and invitation of DEA Compliance.

6. PROCEDURE

Responsibility

Action

6.1 Customer Compliance Files

DEA Compliance

6.1.1 All current customers who have the ability to purchase controlled substances and listed chemicals must have a customer compliance file on record. These files will be created and maintained by DEA Compliance to include:

- Demographic information (completed through questionnaire or other, similar means)
- DEA Registration Validation Results
- Internet search documents
- Email Communications
- Any other information deemed relevant

6.1.2 These files will be maintained and kept as long as the customer is active or 2 years from the date service is discontinued.

SOP #:	SOP- 8279
TITLE:	Suspicious Order Monitoring – Customer Due Diligence

6.2 New Customer Account Verification

6.2.1 Upon being notified of a new customer or location who intends to purchase controlled substances or listed chemicals, the National Account Manager will notify DEA Compliance and supply the following information:

For New Customers

- Customer name and any DBA names
- Customer address and all ship to addresses
- Customer phone and fax numbers
- Customer website address
- Name and contact information for the owner, CEO, or any relevant principals
- DEA registration number(s)
- State license number(s)
- Date requested to begin servicing account
- Customer Class of Trade
- TEVA National Account Manager name
- Monthly forecast projection for all controlled substances expected to be purchased from TEVA

For New Ship To Locations for Existing Customers

- Customer name
- Ship To address
- Customer phone and fax numbers
- DEA registration number
- State license number
- Date requested to begin servicing account
- If available, monthly forecast projection for all controlled substances expected to be purchased from TEVA

DEA Compliance

6.2.2 DEA Compliance will evaluate the customer compliance risk by reviewing the information supplied by Customer Service. Criteria used to evaluate risk include, but will not be limited to, customer responses to Customer Service, information supplied by the customer or TEVA representative, geographic location, type and quantities of products forecasted for purchase. DEA Compliance will also verify that neither the customer nor its principals are on TEVA's Do Not Ship List.

SOP #:	SOP- 8279
TITLE:	Suspicious Order Monitoring – Customer Due Diligence

- 6.2.3 At the conclusion of the compliance risk evaluation, DEA Compliance will notify Customer Service and the National Account Manager of the findings and its recommendation to service or not service the customer based on the compliance risks to TEVA.
- 6.2.4 If the recommendation of DEA Compliance is not to service the customer for controlled substances or listed chemicals, the Suspicious Order Oversight Team and any other relevant parties will be informed of the findings that resulted in the “not service” recommendation.
- 6.2.5 If the customer has been approved to purchase controlled substances and listed chemicals, DEA Compliance will create a customer profile in the DefOPS system.
- 6.2.6 No controlled substances or listed chemicals can be shipped to a new customer or location without the approval of DEA Compliance and an active profile in DefOPS.
- 6.2.7 If the customer refuses to supply any required information, or does not respond in a timely manner to information requests, The Suspicious Order Oversight Team will be informed and will decide the appropriate course of action.

6.3 Ongoing Customer Risk Evaluation

DEA Compliance

- 6.3.1 DEA Compliance will continuously monitor all active customer accounts for suspicious activity and compliance.
- 6.3.2 DEA Compliance will create and maintain a SOM Customer Risk Evaluation Database to evaluate each customer’s compliance risk to TEVA.
- 6.3.3 The criteria used for ongoing risk evaluation will include, but not limited to:
- Number of previously pended orders in DefOPS
 - Number of previous orders reported as suspicious to DEA by TEVA
 - Ratio of Controlled vs. Non Controlled substances ordered
 - Customer’s geographical location
 - Business Classification
 - Internet Searches
 - Industry Trends

SOP #:	SOP- 8279
TITLE:	Suspicious Order Monitoring – Customer Due Diligence

- Information supplied from DEA, Regulatory Agencies, or other sources

6.3.4 Biannually the business relationship with the top high risk customers will be reevaluated by DEA Compliance and the findings of that review shared with the Suspicious Order Oversight Team.

Suspicious Order Oversight Team

6.3.5 Possible action taken by the Suspicious Order Oversight Team may include but not limited to:

- Closely monitor the customer's purchases for 6 months
- Request additional information
- Conduct a site visit
- Require the customer to develop SOPs on anti-diversion
- Require the customer to institute an SOM program that meets DEA requirements
- Require the customer to conduct a risk assessment of some or all of their customers
- Suspend or reduce the customer's ability to order controlled substances
- Terminate the relationship with the customer due to compliance risk

DEA Compliance

6.3.6 If it is the decision of the Suspicious Order Oversight Team is to restrict or terminate a customer's purchasing ability, DEA Compliance will notify Customer Service Management and A/R of that decision in writing.

DEA Compliance

6.3.7 DEA Compliance will make the appropriate changes to the customer's account in the DefOPS system.

6.3.8 DEA Compliance will notify DEA of any suspicious orders, including any action taken to terminate a customer or restrict a customer's ability to order controlled substances or listed chemicals.

6.3.9 DEA Compliance will place any customer that TEVA restricts or terminates their ability to order controlled substances or listed chemicals on the Do Not Ship List per SOP-8278.

6.4 Re-Establishing a Closed or Restricted Account

SOP #:	SOP- 8279
TITLE:	Suspicious Order Monitoring – Customer Due Diligence

Suspicious Order Oversight Team

6.4.1 A customer on TEVA's Do Not Ship List may only be re-opened or re-evaluated per SOP-8278.

6.5 Customer Site Visits

DEA Compliance

6.5.1 At the direction of DEA Compliance Management, direct communication may be warranted between Teva and the customer's SOM Subject Matter Experts, up to and including a site visit in certain situations. Site visits will be conducted per SOP-8280.

7. ATTACHMENTS

N/A

SOP #:	SOP- 8279
TITLE:	Suspicious Order Monitoring -- Customer Due Diligence

QUIZ

1. All current customers who have the ability to purchase controlled substances and listed chemicals must have a customer compliance file on record maintained by DEA Compliance.

TRUE or FALSE

2. No controlled substances or listed chemicals can be shipped to a new customer or location without the approval of DEA Compliance.

TRUE or FALSE

3. All customers must complete an SOM questionnaire to help evaluates their compliance risk to TEVA.

TRUE or FALSE

SIGNATURES

Employee (print name):	
Employee (signature):	Date:

Quiz answers checked for correctness. All questions incorrectly answered were discussed with the employee and understood.

Instructor (signature):	Date:
-------------------------	-------